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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,135	10/03/2003	David J. Pinsky	51917-CA-PCT-US/JPW/AJM/A	2202

7590 02/09/2006

John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,135	PINSKY ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 46-88 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 46-88 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 46-88 are pending in this application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 63-64, 70, drawn to a method for treating a subject at risk for an ischemic disorder or method of treating ischemia-induced inflammation in a subject which comprises administering to the subject a gas comprising carbon monoxide, wherein the ischemic disorder is a peripheral vascular disorder.

II. Claim 63-64, 70, drawn to a method for treating a subject at risk for an ischemic disorder or method of treating ischemia-induced inflammation in a subject which comprises administering to the subject a gas comprising carbon monoxide, wherein the ischemic disorder is a venous thrombosis.

III. Claim 63-64, drawn to a method for treating a subject at risk for an ischemic disorder which comprises administering to the subject a gas comprising carbon monoxide, wherein the ischemic disorder is a pulmonary embolus.

IV. Claim 63-64, 70, drawn to a method for treating a subject at risk for an ischemic disorder or method of treating ischemia-induced inflammation in a subject which comprises administering to the subject a gas comprising carbon monoxide, wherein the ischemic disorder is a myocardial infarction.

V. Claim 63-64, 70, drawn to a method for treating a subject at risk for an ischemic disorder or method of treating ischemia-induced inflammation in a subject which comprises administering to the subject a gas comprising carbon monoxide, wherein the ischemic disorder is a transient ischemic attack.

VI. Claim 63-64, drawn to a method for treating a subject at risk for an ischemic disorder or method of treating ischemia-induced inflammation in a subject which comprises administering to the subject a gas comprising carbon monoxide, wherein the ischemic disorder is a lung ischemia.

VII. Claim 63-64, 70, drawn to a method for treating a subject at risk for an ischemic disorder or method of treating ischemia-induced inflammation in a subject which comprises administering to the subject a gas comprising carbon monoxide, wherein the ischemic disorder is unstable angina.

VIII. Claim 63-64, 70, drawn to a method for treating a subject at risk for an ischemic disorder or method of treating ischemia-induced inflammation in a subject which comprises administering to the subject a gas comprising carbon monoxide, wherein the ischemic disorder is reversible ischemic neurological deficit.

IX. Claim 63-64, drawn to a method for treating a subject at risk for an ischemic disorder or method of treating ischemia-induced inflammation in

a subject which comprises administering to the subject a gas comprising carbon monoxide, wherein the ischemic disorder is adjunct thrombolytic activity.

X. Claim 63-64, drawn to a method for treating a subject at risk for an ischemic disorder or method of treating ischemia-induced inflammation in a subject which comprises administering to the subject a gas comprising carbon monoxide, wherein the ischemic disorder is excessive clotting condition.

XI. Claim 63-64, 70, drawn to a method for treating a subject at risk for an ischemic disorder or method of treating ischemia-induced inflammation in a subject which comprises administering to the subject a gas comprising carbon monoxide, wherein the ischemic disorder is sickle cell anemia.

XII. Claim 63-64, 66, 69, 70, drawn to a method for treating a subject at risk for an ischemic disorder or method of treating ischemia-induced inflammation in a subject which comprises administering to the subject a gas comprising carbon monoxide, wherein the ischemic disorder is a stroke disorder.

XIII. Claim 64, drawn to a method for treating a subject at risk for an ischemic disorder which comprises administering to the subject a gas comprising carbon monoxide, wherein the subject is undergoing abdominal surgery.

XIV. Claims 64-65, 69, drawn to a method for treating a subject at risk for an ischemic disorder which comprises administering to the subject a gas comprising carbon monoxide, wherein the subject is undergoing organ transplantation surgery.

XV. Claim 67, drawn to a method for improving preservation of an organ to be transplanted from a donor which comprises administering to the donor a gas comprising carbon monoxide.

XVI. Claim 73, drawn to a method for treating inflammation characterized by induction of heme oxygenase-1 (HO-1) in a subject comprising administering to the subject an effective amount of carbon monoxide gas.

XVII. Claim 74, drawn to a method for the "medical treatment" of a subject comprising administering to the subject a gas composition comprising carbon monoxide at 0.0001% to 2% in an inert gas.

XVIII. Claims 75-76, drawn to a method for reducing oxygen-mediated damage to an organ or tissue associated with surgery comprising administering to a surgical patient carbon monoxide in an amount and over a period of time sufficient to reduce the oxygen-mediated damage.

XIX. Claims 77-88, drawn to a medical gas composition comprising carbon monoxide.

Claims 46-62, 68 and 71-72 link inventions I to XIV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 46-62, 68 and 71-72. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The distinctness of the inventions is evident from the multiple divergent uses of the carbon monoxide gas composition. Applicant's multiple divergent uses are evidence that the composition can be used in materially different processes. The various different disorders or conditions are distinct from the others, and treatments for each disorder or condition must be tailored for that particular disorder or condition in the absence of a nexus type teaching. Treatments for the various disorders or conditions claimed herein are not necessarily the same for each disorders or conditions, and the special circumstances of each distinct disorder or condition must be taken into account. For example, in the absence of a nexus type teaching, treatment for a peripheral vascular disorder would be considered a separate subject for inventive effort from a treatment for pulmonary embolus or sickle cell anemia, for example.

Although most of the inventions would find placement in U.S. Patent Classification Class 424, Subclass 699, such unrefined classification is the workings of a classification system that is not well suited for this type of invention and that is not predictive of actual search burden. Here, the search burden would be quite challenging, to say the least. Each separate disorder or condition needs to be separately searched in the non-patent and patent literature for prior art as well as enablement or non-enablement evidence, given the use of a potentially toxic gas. Given the complexities involved in the present invention, i.e. use of a potentially toxic gas to deliver therapeutic benefits for myriad divergent disorders and conditions, the search for even one invention is already of sufficient burden; and the search and examination of more than one invention group would place an undue burden on the Examiner.

For these reasons of distinctness and undue burden, the restriction requirement as set forth above is deemed to be proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
GROUP 1600